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Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 170 to 199, revised as of April 1, 1998, make the following corrections:

1. In § 178.3130(b), on page 364, in the second column, in the first line of number 2 under Alkyl mono- and disulfonic acids, correct ''be'' to read ''to'', and in the same column, at the end of the fourth paragraph, after the words ''such foods have a pH'', add the words ''above 5.0''.

2. In § 178.3620(c)(3), on page 384, in the first column, in the first full paragraph, line 14, after the words ''Loosen the'' correct ''top'' to read ''topmost'' and add the following:

* * * * *

''few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500–milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 2–3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5–milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5–milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5–milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2–3 milliliters per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the''

* * * * *

2.In § 178.3910(a)(2) table, on pages 406 and 407, in the first column, under ''List of substances'', correct the second, third, and fifth entries to read as follows:

* * * * *

α–Butyl–Ω–hydroxypoly(oxypropyl–ene) (CAS Reg. No. 9003-13–8) having a minimum molecular weight of 1000.

α–Lauroyl–Ω–hydroxpoly (oxyethylene) (CAS Reg. No. 9004–81–3) having a minimum molecular weight of 200.

* * * * *

alpha–Alkyl–*omega*–hydroxypoly–(oxyethylene) produced by the condensation of 1 mole of C_{12} – C_{15} straight chain primary alcohols with an average of 3 moles of ethylene oxide (CAS Reg. No. 68002–97–1).

* * * * *

[FR Doc. 99–55505 filed 1–28–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

Indirect Food Additives: Adhesives and Components of Coatings

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 170 to 199, revised as of April 1, 1998, on page 157, second column, § 175.300 is corrected in paragraph (b)(3)(vii)(*a*) by correcting the CAS Reg. No. for 1,4–cyclohexanedicarboxylic to read ''(CAS Reg. No. 1076–97–7)''.

[FR Doc. 99–55504 filed 1–28–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 78N–036L]

RIN 0910–AA01

Laxative Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that the over-the-counter (OTC) stimulant laxative ingredients danthron and phenolphthalein are not generally recognized as safe and effective and are misbranded. FDA is issuing this final rule as part of its ongoing review of OTC drug products after considering data and information on the safety of danthron and phenolphthalein.

EFFECTIVE DATE: January 29, 1999.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Turner, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 21, 1975 (40 FR 12902), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC laxative, antidiarrheal, emetic, and antiemetic drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel), which was the advisory review panel that evaluated data on the active ingredients in these classes. In the advance notice of proposed rulemaking, the Panel recommended Category I (generally recognized as safe and effective and not misbranded) status for the OTC stimulant laxative ingredients danthron and phenolphthalein (40 FR 12902 at 12908 to 12910). The agency concurred with the Panel's Category I classification of these ingredients in the tentative final monograph published in the **Federal Register** of January 15, 1985 (50 FR 2124 at 2152 to 2156).

In the **Federal Register** of September 2, 1997 (62 FR 46223), FDA reopened